

SPL ER/DL Team

Apr 13, 2011

Minutes

Teleconference information:

USA Toll-Free 866-213-2145

Access code: 273 8216

Chair for this meeting: Pat Cowall

1. Reminder -- Teleconference with CMS (Jessica)
 - a. Scheduled for our next er/dl meeting on April 27, 2011, 1 pm EDT
 - b. Please send questions to Jessica Skorups at
"Skorupski, Jessica Dunn [CPGRAUS]" <JSkorups@its.jnj.com>
2. Debrief from the Teleconference with FDA -- DRLS and Import Discussion on March 30. (Pat)
 - a. Pat gave a summary of the teleconference. Minutes from the meeting are out for review. They will be posted on the wiki once they are completed.
3. Jean (Hospira) got a letter from FDA saying that the effective date in the highlights section didn't match the current label. Issue is that the SPL effective date automatically fills this field. If there is an update to non-COL data, then new SPL is created and they have been entering a new effective date for the SPL. FDA review division sent them a letter telling them it needs to match the update of the last COL. Is anyone else getting this feedback? (Jean Kirkeleit Davis)
 - a. Jean will contact Lonnie to ask his advice and get back with us.
 - b. BMS Jackie – they have had an internal meeting to discuss this. For PLR, they keep the effective time on the SPL the same as the effective date of the USPI. They update the effective time of the individual section. They update the version number.
 - c. Merck: They do the same thing.
 - d. Ask Jean to update us on May 11th meeting.
4. Removing old product SPL files from DailyMed if the NDA and/or NDCs have been withdrawn from the NDC directory (Jackie Mohns, BMS)
 - a. NLM sent back an error saying that the NDAs and/or NDCs were withdrawn. Problem is that ANDA has already been withdrawn. There is notice in the Federal Register. Not recognizing the product. Reporting an NDA/NDC that isn't being recognized. Wouldn't remove:
 - b. Jackie update:
 - Must convert to R4 and delist as you would any other newer product. for NDCs not in the NDC directory, she removed the old NDCs from the SPL file.
 - Submit it...and expect to get an error message back...since the NDAs isn't active,
 - You need to ask Lonnie for an override. Send Lonnie the following info
 1. Core ID
 2. NDCs that were in the SPL file that needed to be delisted
 3. Application number.
 - He said it would take time to get it removed.

5. Establishment registration SPL. Issue with DUNS numbers –duplicate. (Paula Finn)

- a. Background: On 1/3/2011 we successfully submitted our 2011 establishment registration. On 4/8/11 we submitted an establishment registration to update our official correspondent contact only; there were no other changes to the establishments. On 4/11/11 we received an error message for two of the establishments because of DUNS.
- b. In one situation, there is a D&B conflict and we are not sure how to resolve. On the D&B website, if searching by company name and country (France), the DUNS search function provides the correct DUNS. If that DUNS is then searched for on the D&B website by DUNS and country (France) a different company shows up. It appears that two companies share one DUNS, or there is a software glitch.
 - emailed Lonnie, but no answer yet.
 - suggest contacting DUN and Bradstreet.
- c. In the other situation, we have a campus of several establishments on the same street. Each individual street address will have its own DUNS. Historically, the FDA wanted us to combine all street addresses into a single campus, based on the first establishment that was registered. This now results in an error.
 - Multiple DUNS numbers and multiple FEI numbers. How do they want you to convert to 1 campus?
 - Cory/Novartis: 1 FEI number and multiple DUNS number. They use one FEI/DUNS number for one of the facilities
 - information must match.
 - emailed Lonnie and are waiting for a response.
 - Will report back.
- d. We have sent Lonnie/SPL an email with these situations but we have not heard back yet. Does anyone else have experience with this?

6. Legacy NDC codes from old paper process. Has anyone delisted the “old” NDCs from the manufacturer only product. Need to get clarification on all the specific scenarios as to who must drug list what:

- a. Pat to develop scenarios and discuss each with Paul Loebach.

Upcoming Meetings being planned:

- Discussion with CMS: April 27, 2011: Jessica
- Discussion with First DataBank: Michelle

Followup with outcomes:

- Paula Finn: problems with establishment information for “campuses” and French.